

Alternative Methodology noted in Red below.

SECTION 10. REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT

SEC. 10. THE USE OF AN HMRT UNIT REPRESENTS EMERGING CANCER TREATMENT TECHNOLOGY AND CONSEQUENTLY PROVIDES A MIXTURE OF BOTH TREATMENT AND RESEARCH USES. THIS SECTION OF THE CON REVIEW STANDARDS FOR MRT SERVICES/UNITS RECOGNIZES THE UNIQUE NATURE OF THIS TECHNOLOGY.

(1) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) AN APPLICANT IS A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN THE STATE OF MICHIGAN **THAT CONSISTS OF THE FOLLOWING:**

(I) ALL ENTITIES WITH OWNERSHIP INTEREST IN THE APPLICANT ENTITY OWN AT LEAST ONE HOSPITAL LICENSED IN THE STATE OF MICHIGAN UNDER PART 215 OF THE CODE.

(II) NO OWNERSHIP ENTITIES CURRENTLY OPERATE AN HMRT UNIT, OR HAVE A VALID CON ISSUED UNDER PART 222 TO OPERATE A HMRT UNIT, UNLESS THE OWNERSHIP ENTITY TREATED PATIENTS WITH THE HMRT UNIT PRIOR TO THE EFFECTIVE DATE OF THESE STANDARDS.

(B) THE APPLICANT SHALL HAVE COLLECTIVELY PERFORMED AT LEAST 200,000 ETVS IN THE MOST RECENT 12-MONTHS FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(I) THE SUM OF ALL ETVS PERFORMED AT MRT FACILITIES WHOLLY OWNED BY OWNERSHIP ENTITIES; PLUS

(II) THE PERCENTAGE OF ETVS PERFORMED AT MRT FACILITIES PARTIALLY OWNED BY OWNERSHIP ENTITIES, EQUAL TO THE PERCENTAGE OF OWNERSHIP OF THE FACILITY HELD BY THE OWNERSHIP ENTITIES.

AN APPLICANT IS A COLLABORATIVE THAT CONSISTS OF AT LEAST 40% OF ALL MICHIGAN HOSPITAL MRT SERVICES WITH MORE THAN 30,000 ETVS PERFORMED IN THE MOST RECENT 12-MONTH PERIOD OF DATA AVAILABLE TO THE DEPARTMENT.

~~—(C) THE COLLABORATIVE SHALL INCLUDE HOSPITAL MRT SERVICES FROM MORE THAN ONE PLANNING AREA FROM EITHER OR BOTH OF THE FOLLOWING:~~

~~—(I) THE PARTICIPATING SERVICES UNDER SUBSECTION (B).~~

~~—(II) HOSPITAL MRT SERVICES WITH THE HIGHEST NUMBER ETVS IN A PLANNING AREA BASED ON THE MOST RECENT 12-MONTH PERIOD OF DATA AVAILABLE TO THE DEPARTMENT.~~

~~—(D) MRT SERVICES THAT ARE ALREADY PART OF A COLLABORATIVE APPLICATION UNDER THIS SECTION FOR AN MRT SERVICE UTILIZING AN HMRT UNIT OR PART OF AN EXISTING COLLABORATIVE UTILIZING AN HMRT UNIT APPROVED UNDER THIS SECTION SHALL NOT BE INCLUDED IN THE APPLICATION.~~

(E) AN APPLICANT SHALL PROVIDE DOCUMENTATION OF ITS PROCESS, POLICY AND PROCEDURES THAT WILL ALLOW ANY OTHER INTERESTED ENTITIES TO PARTICIPATE IN THE COLLABORATIVE UTILIZING AN HMRT UNIT.

(F) AN APPLICANT SHALL PROVIDE AN IMPLEMENTATION PLAN FOR FINANCING AND OPERATING THE PROPOSED MRT SERVICE UTILIZING AN HMRT UNIT INCLUDING, BUT NOT LIMITED TO, HOW PHYSICIAN STAFF PRIVILEGES, PATIENT REVIEW, PATIENT SELECTION, AND PATIENT CARE MANAGEMENT SHALL BE DETERMINED.

(G) AN APPLICANT SHALL INDICATE THAT ITS PROPOSED HMRT UNIT WILL BE AVAILABLE TO BOTH ADULT AND PEDIATRIC PATIENTS.

(H) AN APPLICANT SHALL DEMONSTRATE THAT THE MRT SERVICE UTILIZING AN HMRT UNIT WILL HAVE SIMULATION CAPABILITIES AVAILABLE FOR USE IN TREATMENT PLANNING.

(2) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL ALSO DEMONSTRATE COMPLIANCE WITH THE REQUIREMENTS OF SECTION 4(3).

[NOTE: Other methodologies accomplishing similar outcomes could also be considered.]